



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

KALLOO et al

Atty. Ref.: 2784-25

Serial No: 09/815,336

TC/A.U.: 3739

Filed: March 23, 2001

Examiner: Shay, David

For: METHODS AND DEVICES FOR DIAGNOSTIC AND
THERAPEUTIC INTERVENTIONS IN THE PERITONEAL CAVITY

* * * * *

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 CFR §1.131

1. We, Anthony Nicolas Kalloo and Sergey Veniaminovich Kantsevov, declare as follows:

2. We are the inventors of the subject matter claimed in the Patent Application identified above.

3. We understand that the Patent Office has rejected certain claims of this patent application as allegedly being "anticipated" under 35 USC 102(e) by U.S. Patent No. 6,689,062 (Mesallum), filed November 22, 2000 and which claims the benefit of provisional Application No. 60/167,147, filed November 23, 1999.

4. We understand that the Patent Office has also rejected certain claims of this patent application as allegedly being "obvious" under 35 USC 103(a) from U.S. Patent No. 6,689,062.

5. The subject matter disclosed and claimed in our patent application was conceived before Mesallum's claimed November 23, 1999 effective filing date and we worked diligently toward actual and constructive reduction to practice from a date before November 23, 1999 to the filing date of our provisional Application.

BEST AVAILABLE COPY

6. Attached as Exhibit A are Meeting Minutes, redacted to protect confidentiality. These Meeting Minutes bear dates of before November 23, 1999 (the actual dates have been redacted to protect confidentiality). Pages 5, 6, 11 and Appendix 5 all evidence the conception of this invention before the filing date of the first Mesallum application. More specifically, the meeting minutes confirm concept of a method for accessing an interior of a cavity of a mammal, said method comprising: positioning an elongated flexible conduit to extend from an exterior of the mammal through a natural orifice into and along at least a portion of the digestive tract to a target wall segment in the digestive tract; forming an incision in said target wall segment; advancing a distal end of said flexible conduit so that the distal end of said conduit extends through said wall; after forming said incision and advancing the distal end of said flexible conduit through said wall, anchoring said distal end with respect to said wall; advancing an endoscope through said conduit so that a distal end of said endoscope is disposed adjacent or distal to said distal end of said conduit; viewing at least one of a tissue and an organ within said cavity; releasing said anchor; withdrawing said conduit and said endoscope through said wall; and closing said incision.

7. The Animal Research Protocol attached as Exhibit B further evidences our earlier conception of this invention and our diligence to reduce the invention to practice and the associated letter corroborates the same. The letter and Animal Research Protocol bear an initial date of before November 23, 1999 (the actual dates have been redacted to protect confidentiality).

8. The letter attached as Exhibit C is our reply to the Animal Care and Use Committee, which also bears a date of before November 23, 1999 (the actual date has been redacted to protect confidentiality).

9. The laboratory notes attached as Exhibit D detail the animal studies conducted over several months pursuant to the Animal Research Protocol. These laboratory notes evidence our diligence toward reducing our invention to practice starting before November 23, 1999 (the actual date has been redacted to protect

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Serial No. 09/815,336

confidentiality). The results of our preliminary studies were reported in our abstract in Gastroenterology; 2000, 118; A1039.

10. Following our animal studies we diligently prepared an invention disclosure and submitted it to Johns Hopkins University Office of Technology Licensing. The Invention Disclosure was received by the Office of Technology License on December 10, 1999 (Exhibit E).

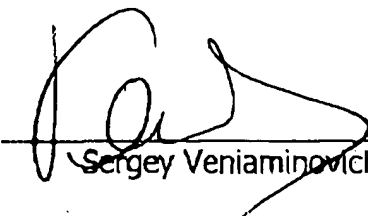
11. Thereafter, we diligently worked with Johns Hopkins University patent Counsel to prepare and file our Provisional Application on March 24, 2000.

12. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 11/21/05

By: 
Anthony Nicolas Kalloo

Date: 11/21/05

By: 
Sergey Veniaminovich Kantsevov

Attachment:
Exhibits A - E

Exhibit A

3

-- MEETING MINUTES --
FLEXIBLE TRANSLUMINAL ENDOTHERAPY
"KICK-OFF" MEETING
REDACTED
KIAWAH ISLAND, SC

CONFIDENTIAL

ATTENDEES:

Physicians/Surgeons:

Sydney Chung, MD
Peter Cotton, MD
Christopher Gostout, MD
Robert Hawes, MD

Anthony Kalloo, MD
Sergey Kantsevov, MD, PhD
Jay Pasricha, MD
Ted Trus, MD

Olympus Tokyo

H. Furihata
H. Sasa
H. Shimonaka

A. Taguchi
M. Terada
M. Utsugi

Olympus America

D. Barlow
L. Cosentino
H. Ichikawa

R. Kirchoff
S. Nishigaki
M. Whitman

MODERATED BY DR. HAWES

OPENING REMARKS - MR. TERADA

Olympus pledges its commitment to this group and to the development of transluminal therapy as the future of endoscopy.

REDACTED

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PRESENTATION - DR. KALLOO

Johns Hopkins has a 5,000 sq. ft. Research Center for Minimally Invasive Procedures. The center has animal facilities and a full complement of radiology, anesthesia and monitoring equipment.

Dr. Kalloo showed the concept of using a sheath to protect a sterile endoscope prior to passage through the gut wall. A needle electrode could be placed at the tip of the sheath to create a hole to allow the sheath to exit the stomach wall. Balloons could be placed on the

tip of the sheath to anchor it to the stomach wall. A sheath of this type could be used for pseudocyst drainage or cholecystectomy. (Appendix 5)

Dr. Kalloo presented a concept for a precurved (semi-circular) needle which is temporally straightened by the applicator tube. (Appendix 5)

DISCUSSION

A firm anchor of the ports to the abdominal wall is a problem in laparoscopy. To solve this a variety of screw threads and balloon cuffs have been commercialized. Perhaps a purse-string suture could be used as well.

The stomach makes a better port of access into the abdomen than the colon, since the stomach heals so well.

REDACTED

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REDACTED

ESTABLISHED DIRECTIONS		
PROJECT	INSTITUTION	DEVICES
REDACTED	REDACTED	(REDACTED es
Cholecystectomy (i.e., organ removal through the gut wall)	Johns Hopkins	Sterile Sleeve to enter the gut wall, etc.

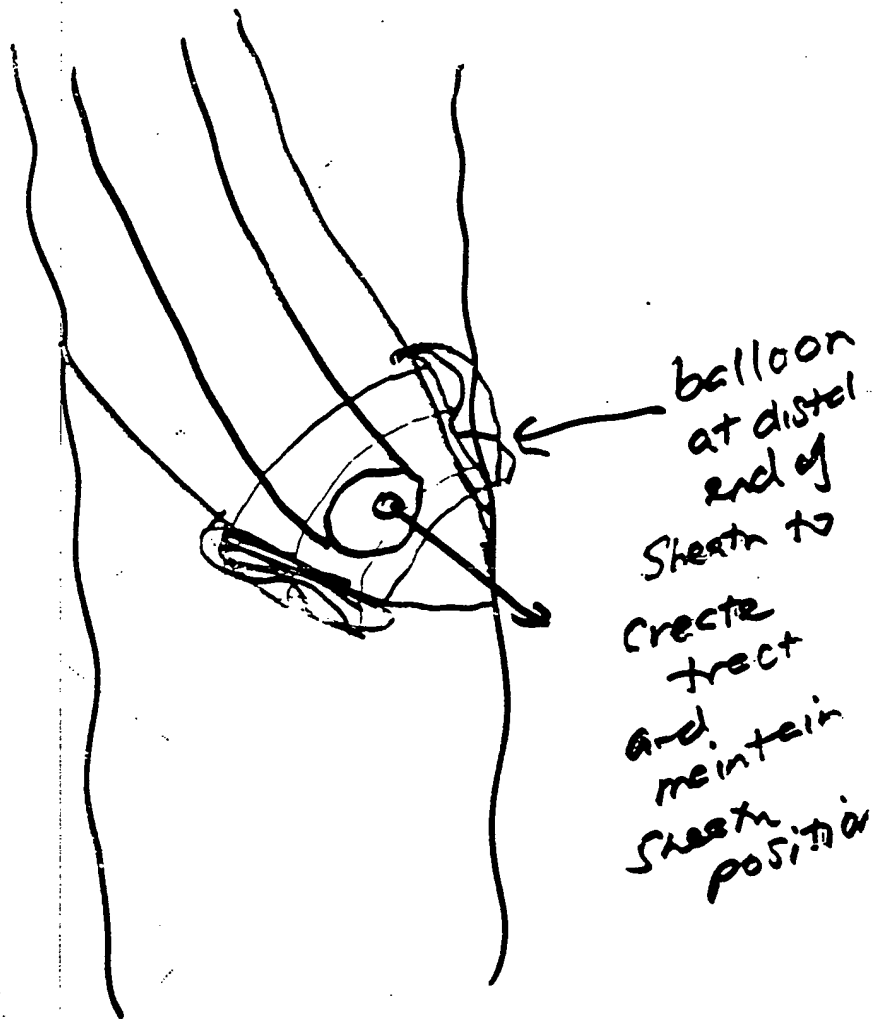
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APPENDIX 5

PRESENTATION:

DR. KALLOO

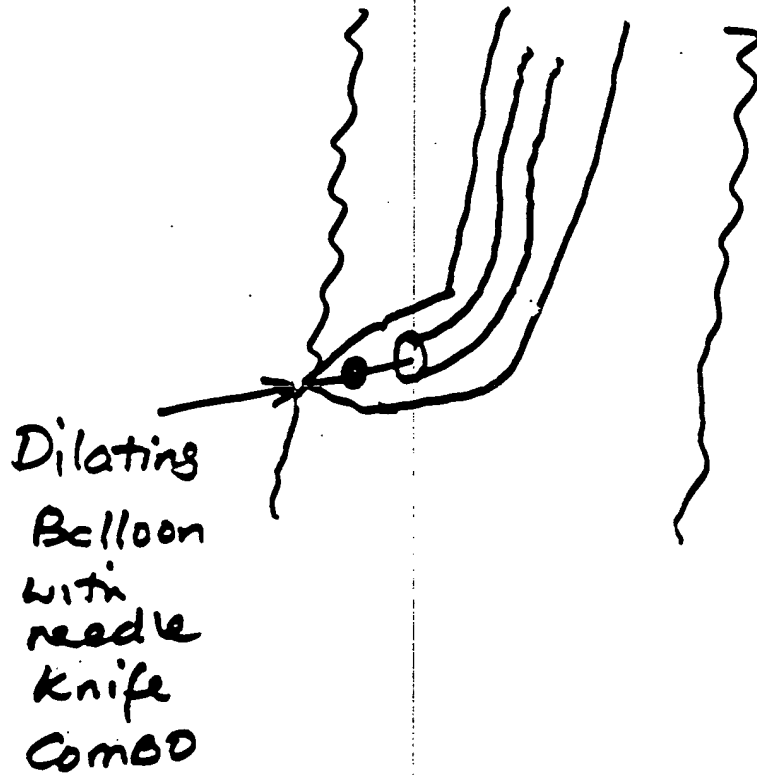
①



ENDOSCOPIC SHEATH TO MAINTAIN
STERILITY OF ENDOSCOPE SO THAT
it can be placed into peritoneal
cavity

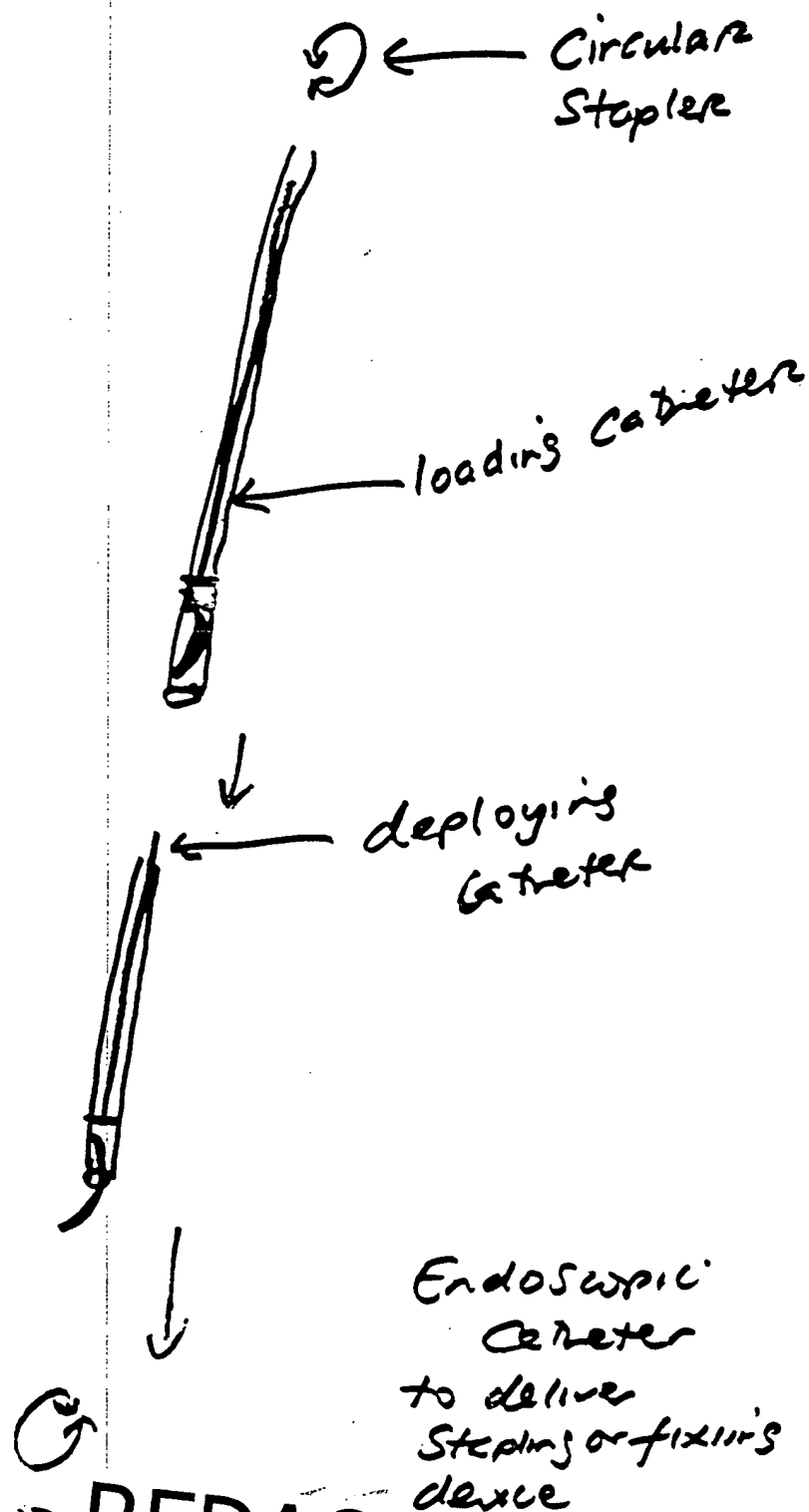
Tony KALLOO REDACTED

②



Tony KALLOO REDACTED

③



Tony KALLOD REDACTED

Exhibit B

JOHNS HOPKINS UNIVERSITY

Animal Care and Use Committee

720 Rutland Avenue, Ross 459
Baltimore, Maryland 21205
(410) 955-3273 / FAX (410) 502-5068

REDACTED

Dear Dr. Anthony N Kalloo

On REDACTED, the Animal Care and Use Committee approved the following research protocol of which you are the Principal Investigator. A copy of the approved protocol is attached. Any modifications to the protocol originally submitted are noted on the form.

Proto#: SW99M75

TITLE : Flexible endoscopic cholecystectomy

Expiration Date: REDACTED

The appropriate protocol numbers must be used in the submission of applications through the Office of Research Administration. Protocol numbers will also be requested by Animal Services when animal orders are placed. The approval is for one (1) year only. Protocols may be renewed twice unless otherwise noted on the last page of your copy of the approval. Any substantive changes in or amendments to protocols must be submitted to the committee for its approval. This should be done as soon as the modified procedures are developed and before they are implemented. Application for approval of protocol amendments and modifications should be made in the same way as the original protocol.

For help in budget planning, Animal Services will be happy to estimate the purchase and care costs for you at the time of grant budget preparation. For up-to-date pricing information contact Animal Services at x5-3713.

GRANT APPLICATION PROCEDURES

PROTOCOL REVIEW

Effective January 1, 1986, all Public Health Service (PHS) and National Science Foundation (NSF) grant and contract applications involving the use of vertebrate animals require certification of review and approval of all proposed animal use by the Animal Care and Use Committee. Most private sponsors have adopted similar procedures and the Johns Hopkins Medical Institutions (JHMI) requires protocol approval for ALL vertebrate animal use irrespective of funding. Beginning November 1989, regulations resulting from recent amendments to the Animal Welfare Act force annual review of all experimental procedures using live vertebrate animals.

INSTRUCTIONS CONTINUED ON REVERSE

JOHNS HOPKINS
UNIVERSITY

Animal Care and Use Committee

720 Rutland Avenue, Ross 459
Baltimore, Maryland 21205
(410) 955-3273 / FAX (410) 502-5068

REDACTED

To: Dr. Anthony Kalloo

From: Richard J. Traystman, Ph.D., Chairman *RT*
The Johns Hopkins University School of Medicine
Animal Care and Use Committee

Re: Animal Research Protocol - Flexible Endoscopic Cholecystectomy

The Animal Care and Use Committee reviewed your animal research protocol on **REDACTED**. Your protocol was approved pending clarification of the following information:

1. Are antibiotics administered for this procedure? If yes, state the type, dose, frequency and duration of administration.

Please mail your response to the Animal Care and Use Committee, c/o the Division of Comparative Medicine, 459S Ross. You may not use this protocol to order animals or for research grant applications until the requested information is received and approved.

If you have questions or need assistance, please contact the Animal Care and Use Committee Office at 955-3273.

JOHNS HOPKINS ANIMAL CARE AND USE COMMITTEE PROTOCOL REVIEW FORM

PROTOCOL NO. SW99m75

DATE REC'D: REDACTED

EXPIRATION DATE: _____

REVIEWER: _____

☐ Log ☐ Database

For ACUC Use Only

☐ New Protocol

☒ 3rd Year Replacement of Protocol No _____

Responsible Faculty Member: Anthony N. Kalloo M.D.

Phone No: 410-955-9696

E-Mail Address: akalloo@welchlink.welch.jhu.edu

Fax No: 410-614-7340

JHU Internal Address: 1830 E. Monument St. Rm. 419
(campus mail)

Faculty Title: Associate Professor of Medicine

Primary

Department: Gastroenterology

Co-Investigators: Sergey I. Kantsevov M.D., Cheryl Vaughn R.N.

Title of Protocol: Flexible Endoscopic Cholecystectomy

Is this protocol for a pending grant application(s)? If so, what is/was the submission date(s) and sponsor(s) Grant applicatio
to be submitted when there is Institutional approval.

1. RESEARCH ANIMAL (one species per protocol)

Species	Strain/Stock	Domestic	Supplier	Archer Farms	Weight/ Age	Approx 70-80 lb	Number/Year	50
Swine								

2. MAJOR CATEGORIES OF RESEARCH USE Please answer all questions yes or no. All "yes" responses must be completely described in the Protocol Narrative. Categories refer to in vivo procedures only.

Yes No

- ☒ ☐ a. Euthanize and harvest tissue (see Section 6).
- ☐ ☒ b. Immunization. Describe antigen, adjuvant, route of immunization, method of obtaining blood as well as volume and frequency.
- ☒ ☐ c. Physiological Measurements. If includes surgery, see Section 4.
- ☐ ☒ d. Dietary Manipulations, e.g. caloric restriction, specific constituent restriction.
- ☐ ☒ e. Pharmacology/Toxicology: Describe agent(s), route of administration, etc.
- ☐ ☒ f. Behavioral Studies.
- ☐ ☒ g. Environmental Stress, e.g. cold, noise, restraint, forced exercises, etc.
- ☐ ☒ h. Irradiation. Describe type of irradiation and facility to be used.
- ☐ ☒ i. Biohazardous Materials, e.g. carcinogens, radioactive materials, etc. Be sure to notify JHMI Safety Office.
- ☐ ☒ j. Infectious Agents. (Indicate JHMI Safety Office Approval # _____).
- ☐ ☒ k. Trauma.
- ☐ ☒ l. Experimental oncology or tumor transplantation study.
- ☐ ☒ m. Breeding Colony.
- ☐ ☒ n. Teaching.
- ☐ ☒ o. Other. Please specify. _____

3. Will animals be housed outside of the central animal facilities for greater than 12 hours in conjunction with this protocol?
☐ Yes ☒ No. If yes, where? _____ EXPLAIN REASON FOR THIS IN PROTOCOL NARRATIVE.

4. Non-Surgical Procedures ☐ Yes ☒ No Where (lab, OR, etc) is (are) procedure(s) performed? Turner 319
Anesthetic used: _____
Person(s) performing the procedure: _____

5. **SURGERY**

- a. Non-survival surgery (animal does not awaken from anesthesia) Yes X No

Where is surgery performed: _____

Anesthetic used: _____

Person(s) doing surgery: _____

- b. Survival surgery (animal allowed to recover for any length of time) X Yes No

Where is surgery performed: Traylor 319

Anesthetic used and dosage: IM: Acepromazine 1.1 mg/kg, Ketamine 15-20 mg/kg, Atropine 0.08 mg/kg, IV: Sodium Pentathol 15 mg/kg, Isoflurane 1.5%-2.0%

Person(s) doing surgery: Dr. Anthony Kallio

Person(s) providing post-operative care: Carolyn Magee

Postoperative analgesic(s) and dosage: Buprenorphine 0.1 mg/kg

How long will animal survive after surgery: 2-12 months

6. **PAIN AND DISTRESS** - Indicate THE NUMBERS of animals included in this protocol for each of the categories below. Please clarify or amplify in Protocol Narrative.

- C. Procedures which cause no pain or significant distress in the absence of anesthesia (including approved euthanasia methods).
- * 50 D. Procedures are potentially painful, but anesthetics, tranquilizers, etc. are given to alleviate pain and distress.
- * E. Procedures involve pain or distress which is not alleviated (JUSTIFICATION FOR NOT PROVIDING SUCH ALLEVIATION MUST BE PROVIDED IN THE PROTOCOL NARRATIVE).

* For all animals listed in Category "D" or "E" in Section 6 (Pain and Distress), I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted below and have found no valid alternative to any procedure described herein which may cause more than momentary pain or distress. The methods and sources used in my search included the following:

<u> </u> Animal Welfare Information Center (AWIC)	<u> </u> AGRICOLA (WelchWeb)
<u> </u> <http://nervet.wustl.edu/AWIC.html>	<u> </u> MedLine (WelchWeb)
<u> </u> BIOSIS <http://www.biosis.org>	<u> </u> Specialists in the Field (provide names)
<u> </u> Other (specify):	<u> </u>

7. METHOD OF EUTHANASIA: (State dose and route) Pentobarbital 100 mg/kg, Supersaturated Potassium Chloride 20 cc IV

8. **PROTOCOL NARRATIVE**: Attach a narrative describing all procedures. Following instructions and format shown on the "Instructions For Completing ACUC Protocol Review Forms".

I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.

I have provided an accurate description of the animal care and use protocol to be followed in the proposed use of animals. I understand that federal and institutional regulations require that significant changes must be approved prior to implementation. I assume responsibility for compliance with such regulations by all personnel involved with this protocol. NOTE: In the School of Hygiene and Public Health, Coinvestigators must also sign the protocol.

Responsible Faculty
Member's Signature

[Signature]

Date

REDACTED

- ☐ Approved as submitted ☐ Disapproved
- ☐ Approved with modifications noted on the approval letter

Committee Chairperson's Signature

[Signature]

Date

REDACTED

IF YOU INDICATED ANIMALS IN CATEGORY "D" OR "E" ABOVE, PLEASE READ BELOW: For all animals listed in Category "D" or "E" in Section 6 (Pain and Distress), I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted below and have found no valid alternative to any procedure described herein which may cause more than momentary pain or distress. The methods and sources used in my search included the following:

☐ Animal Welfare Information Center (<http://www.nal.usda.gov/awic/>) ☐ AGRICOLA (Welchweb, WorldCat)
☒ CancerLit (Welchweb, Medline - OVID) ☐ FirstSearch (Welchweb, WorldCat) ☒ MedLine (Welchweb)

KEYWORDS USED DURING SEARCH:

Cholecystectomy, Pain, Animal

Date of Search: REDACTED Years Covered By The Search: No limit

Number of References (Hits): 22

Specialists in the Field Who Were Consulted (provide names) Dr. Mark Talamini

Other (specify) _____

A. PROTOCOL SUMMARY

1. Species and Number of Animals-

Fifty (50) either sex, adult swine, divided into three groups (three phases), will be studied

PHASE 1: Establishment of successful Flexible Endoscopic Peritoneoscopy (FEP). This will include the following:

- (a). Experiments in the animal laboratory on pigs to develop skills of entering the peritoneal cavity via the intestinal wall (with use of protective endoscopic shield) and closure of the gastric wall incision.
- (b). Development of skills in Flexible Endoscopic Suturing and Ligation in pig model.
- (c). Long-term (1 week) survival with follow-up necropsy on animals having FEP.

PHASE 2: Development of technique of Flexible Endoscopic Cholecystectomy (FEC). This will entail the following: Open laparotomy combined with FEC. During this step the development of specific dissection, retraction and gallbladder removal techniques will be accomplished.

Step 1: Dissection of gallbladder from fossa with transection of the retrocystic tissue.

Step 2: Dissection of the cystic duct and artery.

Step 3: Ligation of cystic artery.

Step 4: Ligation of cystic duct.

Step 5: Needle puncture and decompression of gallbladder.

Step 6: Stapling and transection of the cystic duct.

Step 7: Removal of gallbladder.

PHASE 3: Successful FEC with long-term animal survival. Once successful removal of the gallbladder has been performed then long-term survival studies with necropsies at 1, 3, and 6 months. The goal of necropsy will be to evaluate overall animal recovery from the surgery and to evaluate for delayed complications such as bile duct stricture.

2. Purpose- The purpose of this study is to test and evaluate the feasibility of Flexible Endoscopic Cholecystectomy using the swine biliary system. The key outcome measure is maintenance of a functional biliary system, with no adverse effects on the animal.

Traditional cholecystectomies (surgical and laparoscopic) both come with disadvantages such as, incisions into the peritoneal cavity resulting in postoperative scars, possible infection and postoperative hernias. Though mortality rate with the surgical and laparoscopic cholecystectomy have dropped to 0.17% (1), and 0.07% (2,3,4,5) respectively the major drawback remains the necessity of entering the peritoneal cavity, resulting in scars, possible infection and postoperative hernias.

In 1996 the average total charge for an in-hospital laparoscopic cholecystectomy was \$13,940 and \$15,380 for an open cholecystectomy. Average length of stay for a laparoscopic cholecystectomy was 3.7 days and 6.12 days for open cholecystectomy.

RATIONALE FOR FEC:

1). Less invasive procedure with reduction in post-operative morbidity such as abdominal pain.

2). Shortened or no hospital stay since theoretically the procedure may be on an outpatient basis.

3). Significant cost saving as compared to existing laparoscopic and surgical cholecystectomy.

4). Cosmetically a perfect procedure.

FEC is the next logical step in development of minimally invasive cholecystectomy. The procedure will consist of upper endoscopy via an already existing natural entrance (mouth), incision of the intestinal wall to enter the peritoneal cavity, removal of the gallbladder and closure of the gastric wall. FEC will not require a skin incision. This will result in a perfect cosmetic effect, entirely eliminating the possibility of postoperative hernias. Since nerves and muscles of abdominal wall will not be incised, FEC will be painless. This will make FEC potentially an outpatient procedure. The swine model was chosen as the experimental species for this study for the following reasons:

- 1). This model has been used successfully in the past to evaluate the biliary system.

- 2). The size of the swine biliary system provides a technically feasible device evaluation.

- 3). The swine is relatively easy to care for long term. Repeated monitoring can be performed with the relative ease compared to other animal models.

3. Experimental Protocol-

I. Pretreatment Protocol:

At approximately 12-24 hours prior to the procedure, all solid food will be removed from the animal's cage. A detailed daily care record will be started at this time. The pig will be premedicated with an IM injection (using aseptic technique) Acepromazine 1.1 mg/kg, Ketamine 15-20 mg/kg, and Atropine 0.08 mg/kg. An IV line (angiocath) is placed in an ear vein and Sodium Pentathol 15 mg/kg is administered. The animal is then intubated with a cuffed endotracheal tube.

II. Experimental Manipulations:

Phase 1: Establishment of successful Flexible Endoscopic Peritoneoscopy

Phase 2: Development of technique of endoscopic cholecystectomy

Phase 3: Successful FEC with long-term animal survival

The onset of each individual phase will begin the same. It is as follow: After placing the animal on the operating table in supine position, the ventilator will be connected and ventilation started. Oxygen will be set at approximately 2.5L/min, and the animal will breathe Isoflurane

1.5%-2.0%. Expired CO₂ will be continuously monitored throughout the procedure. A rectal probe will be placed and secured.

III. Surgical Technique:

Phase 1 will last approximately 2-3 months. After adequate anesthesia has been established, and the animal is properly positioned, the endoscopist will concentrate on developing skills in Flexible Endoscopic Suturing and Ligation in the pig. Using a protective endoscopic shield (to maintain sterility of the endoscope), the physician will then develop the necessary skills to enter the peritoneal cavity via the intestinal wall and closure of the gastric wall incision. Those animals having FEP will have a necropsy in 1 week.

Phase 2 will last approximately 3-6 months. After adequate anesthesia has been established the endoscopist will now concentrate on developing the technique of FEC. During this step the development of specific dissection, retraction and gallbladder removal techniques will be accomplished (the steps for this phase were previously outlined).

Phase 3 will last approximately 6-12 months. Once successful removal of the gallbladder has been performed then long-term survival studies with necropsy's at 1, 3, and 6 months. The goal of necropsy will be to evaluate overall animal recovery from the surgery and to evaluate for delayed complications such as bile duct stricture.

IV. Post-procedural care and medication:

Early Care: The animal will be carefully observed during the immediate postoperative period for bleeding or other visually observed complications. At first opportunity, the animal will be weaned from the ventilator. The endotracheal tube will be removed when good gag/swallow reflex has returned. Once extubated, and able to maintain sternal recumbency, the animal will be returned to its cage. Rectal temperature will be recorded and if needed, warming blankets will be provided to the animal. All complications will be noted on the animal daily care record.

Long-term Care: Depending on what phase the animal took part in will determine the length of observation. They will continue to be observed, evaluated and medicated as needed for the duration of survival. Postoperative care charts will be maintained on a daily basis. Any complications or changes in the animal's condition, diet, etc will be reported to the investigator immediately. All treatments will be documented on the postoperative care record. Any animal, which becomes ill or shows clinical signs of illness, will have a final cholangiogram, and will be sacrificed immediately. A limited necropsy will be performed by the study Veterinarian and the cause of illness will be determined as much as possible by the Study Pathologist.

4. PAIN AND DISTRESS: Buprenorphine 0.1 mg/kg will be administered for pain Q12h.

5. METHOD OF EUTHANSIA: Immediately following the final cholangiogram and adequate evaluation of the FEC site has been accomplished; the animal will be euthanized by administering Pentobarbital 100 mg/kg IV followed by 20cc of supersaturated Potassium Chloride.

6. QUALIFICATION AND TRAINING: (1). Dr. Anthony N. Kalloo, Principle Investigator is associated professor of Medicine and is Director of Gastrointestinal Endoscopy. He is highly skilled in gastrointestinal endoscopy and has significant experience in animal protocols.

7. ALTERNATIVES: See protocol Review form.

8. REFERENCES:

1. Roslyn JJ, Binns GS, Hughes EF, et al. Open cholecystectomy: A contemporary analysis of 42,474 patients. *Ann. Surg.* 218: 129, 1993.
2. Southern Surgeons club. A prospective analysis of 1518 laparoscopic cholecystectomies. *N. Engl. J. Med.* 324: 1073, 1991.
3. Cushieri A, Dubois F, Mouiel J, et al. The European experience with laparoscopic cholecystectomy. *Am. J. Surg.* 161:385, 1991.
4. Berci G., and Sackier JM. SAGES laparoscopic cholecystectomy study. *Surg. Endosc.* 6: 97, 1992.
5. Liwin DE, Girotti M.J., Poulin EC, et al. Laparoscopic cholecystectomy: Trans-Canada experience with 2201 cases. *Can. J. Surg.* 35: 291, 1992.
6. Mushinski M. Average charges for cholecystectomies in the United States, 1996. *Stat. Bull. Metrop. Insur. Co.* 79: 16, 1998.

Exhibit C



Johns Hopkins
Department of Medicine

Division of Gastroenterology
Room 419 / 1830 Building
1830 E. Monument Street
Baltimore, MD 21205

TEL: (410) 955-9697
FAX (410) 614-7340
Appointments (410) 955-4166

Anthony Kalloo, M.D.
Director of Gastrointestinal Endoscopy
Associate Professor of Medicine

REDACTED

Richard J. Traystman, Ph.D.
Animal Care and Use Committee
720 Rutland Avenue, Ross 459
Baltimore, Maryland 21205

RE: Animal Research Protocol - Flexible Endoscopic Cholecystectomy

Dear Dr. Traystman,

This is in response to your question regarding antibiotics in this particular protocol. Yes, these animals will be receiving antibiotics: **Dual-cillin**, IV at 10,000 units per pound of swine. It will be administered every other day for a total of two doses.

If there are any questions or concerns, please contact me.

Thank you,

Anthony N. Kalloo M.D.
Director GI Endoscopy

Exhibit D

Animal ID:

Surgeon: Kantsevoy, an - Singh

Person Responsible*:

Protocol Number: SW 99 M 75

Telephone: pager: 3 6751

Telephone:

(*for post operative monitoring and care)

Surgery Date:

REDACTED

Time Started: 9³⁰

Time Finished: 12⁰⁰

Anesthesia used (drugs and amount):

TKX 2ccs, Pentathol 4cc IM
Isoflurane 1.5 - 2.0 %

Analgesic drugs used:

none

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Needle-knife incision of gastric wall. Guide-wire inserted into the peritoneal cavity.

Sphincterotome inserted over the guide-wire & enlarged gastric wall incision to 2.0 cm.

Endoscope advanced to peritoneal cavity.

Diagnostic peritoneoscopy. Then liver biopsy. No bleeding. Endoscope withdrawn into the stomach.

Animal sacrificed.

Post-mortem examination: no bleeding, no damage to small or large bowel. Gastric wall incision on anterior wall between body & antrum. No bleeding from gastric wall incision.

Oper: Kasan

Animal ID:

Surgeon: S. Kantsever
an - V. Singh

Person Responsible*:

Protocol Number:

Telephone: 59697

Telephone: pager: 36751

(*for post operative monitoring and care)

Surgery Date:

REDACTED

Time Started:

9¹⁰

Time Finished:

11²⁰

Anesthesia used (drugs and amount):

TKX 2cc Pentathol 4cc IM
Isoflurane 1.5-2%

Analgesic drugs used:

none

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Acute experiment: gastric wall incision with
needle-knife. Jay-wire inserted into the
incision. Sphincter force inserted over the
jay-wire. Incision enlarged to 2 cm. Endoscope
(GIF-160) advanced to peritoneal cavity.
Diagnostic peritoneoscopy. Gastric wall
incision closed with Olympus endoclips.

Animal sacrificed.

Post-mortem examination: no bleeding
from gastric wall incision. No damage
to internal organs. Good closure of
gastric wall incision with endoclips.

Oper: Rater

Animal ID:

Surgeon:

Person Responsible*:

Protocol Number:

Telephone:

Telephone:

(*for post operative monitoring and care)

Surgery Date:

REDACTED

Time Started:

9 AM

Time Finished:

11⁴⁰

Anesthesia used (drugs and amount):

TKX 3cc, Pentathol 5cc IM

Analgesic drugs used:

Isoflurane 1.5-2%

→ none

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Acute experiment:

Gastric wall puncture with needle-knife. Guide-wire inserted into the puncture site. TTS-20 balloon inserted into the peritoneal cavity over the wire. Balloon distended to 20 mm. Balloon collapsed. Endoscope (61F-160) advanced into peritoneal cavity. Peritoneal cavity examined: localized liver, gallbladder, large and small bowel. Endoscope withdrawn into stomach. Gastric wall incision collapsed - 1 endoclip (Olympus) applied.

Animal sacrificed.

Post mortem examination: no bleeding inside peritoneal cavity. No damage to internal organs. Gastric wall incision - on anterior wall between body and antrum.

Oper: Karkay

Animal ID: .

Surgeon: S. Kauteray

Person Responsible: .

(*for post operative monitoring and care)

Protocol Number:

Telephone: pager 4102836751

Telephone:

Surgery Date: REDACTED

Time Started: 9 am

Time Finished: 11:30

Anesthesia used (drugs and amount): TKX 3cc, Pentathol 5cc IM
Isoflurane 1.5 - 2%

Analgesic drugs used: none

Time of anesthetic recovery: .

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Acute experiment: GIF-160 endoscope advanced to the stomach.
Gastric wall punctured with needle-knife. Guide-wire
inserted into the puncture site. Dilating Balloon (TIS-20)
inserted into the puncture site over the guide-wire.
The balloon distended to 20 mm. Balloon collapsed
and endoscope advanced to peritoneal cavity.
Detailed examination performed. Liver biopsy done -
no bleeding. Endoscope removed to the stomach.
Gastric wall incision collapsed - closed with 4 endoclips.
Animal sacrificed.

Postmortem examination: No bleeding from gastric
wall incision or inside the peritoneal cavity.
No injuries to internal organs. Gastric wall
incision is located on anterior wall between
body and antrum of the stomach.

Oper: .

ACUC ANIMAL POST OPERATIVE CARE AND MONITORING RECORD

Animal ID:

Surgeon: S. Kantkary

Person Responsible*: an - V. Singh

Protocol Number: SW 99 M 75

Telephone: pager: 36751

Telephone:

(*for post operative monitoring and care)

Surgery Date: REDACTED Time Started: 9²⁰ Time Finished: 11⁴⁰

Anesthesia used (drugs and amount): TRX 2cc, Pentathol 4cc IM
Isoflurane 1.5-2%

Analgesic drugs used: none

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Acute experiment:

Needle-knife puncture of anterior gastric wall. Guide-wire inserted into peritoneal cavity through the puncture. Sphincterotome inserted into puncture site over the guide-wire. Gastric wall incision enlarged to 2cm. GIF-160 endoscope advanced into the peritoneal cavity. Multiple adhesion - cut with needle-knife. Good visualization of spleen, liver, gallbladder, small bowel, large bowel. Endoscope removed into the stomach. Gastric wall incision closed with 4 Olympus endoclips.

Animal sacrificed.

Postmortem examination: Good closure of gastric wall incision. Gastric wall incision located on anterior wall in the body of stomach. No bleeding inside peritoneal cavity. No organ damage.

Op: Kantkary

Animal ID:
Surgeon: Sergey Kerntsevoy
on: Vik Singh
Person Responsible*:

Protocol Number: SW99M75
Telephone: pager: 36751
Telephone:

(*for post operative monitoring and care)

Surgery Date: REDACTED Time Started: 9³⁰ Time Finished: 12⁰⁰

Anesthesia used (drugs and amount): TKX 3cc, Pentathol 5cc IM
Isoflurane 1.5 - 2 %

Analgesic drugs used: Ø

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Acute experiment:

Needle-knife puncture of gastric wall. Jag-wire
inserted into the puncture site. TTS-20 balloon
(Microvasc) advanced into the puncture site over
the guide-wire. Balloon distended to 20 mm.
Balloon collapsed. GIF-160 upper endoscope
advanced into the peritoneal cavity. Multiple adhesions
between omentum and anterior abdominal wall
- cut with needle-knife. Peritoneal cavity examined
- visualized liver, spleen, gallbladder, large and
small bowel. Endoscope removed into stomach.
Gastric wall incision collapsed - residual opening
closed with 4 endoclips (Olympus).

Animal sacrificed.

Postmortem examination: No damage to internal
organs. No bleeding. Gastric wall incision - on
anterior wall between body and antrum.

Oper: Ramsey

Animal ID:

Surgeon: *Kountzevay*

Ass: *Singh*

Protocol Number: *SW99M75*

Telephone: *paper: 36751*

Person Responsible*:

Telephone:

(*for post operative monitoring and care)

Surgery Date:

REDACTED

Time Started: *9¹⁵*

Time Finished: *11⁵⁰*

Anesthesia used (drugs and amount): *TKX 4 cc, Pentathal 4 cc IM.*
Isoflurane 1.5-2 %

Analgesic drugs used: *none*

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Acute experiment:

Needle-knife incision of gastric wall. Guide-wire advanced into the peritoneal cavity. Sphincterotome placed over guide-wire and gastric wall incision is enlarged to 2 cm. Endoscope (GIF-160) is advanced into the peritoneal cavity. No visible adhesions. Good visualization of spleen, liver, gall bladder, small intestine, large bowel. No active bleeding. The endoscope removed into the stomach. Gastric wall incision is closed with 5 endoclips (Olympus).

Animal sacrificed.

Post-mortem examination: *Good closure of gastric wall incision. No active bleeding. No damage to internal organs. Gastric incision - on anterior wall (between body and antrum of the stomach).*

*Oper. *Pasun**

Animal ID:

Surgeon: Kantsevar

Assist: Singh

Person Responsible*:

Protocol Number: SW99M75

Telephone: pager: 36751

Telephone:

(*for post operative monitoring and care)

Surgery Date:

REDACTED

Time Started:

9³⁰

Time Finished:

12¹⁵

Anesthesia used (drugs and amount):

TKX 2 cc, Pentathol 4 cc IM
Isoflurane 1.5-2 %

Analgesic drugs used:

Ø

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Acute experiment:

Gastric wall punctured with needle-knife. Jaws were inserted into the puncture site. Microvascure TTS balloon inserted over the guide-wire and distended to 20mm. GIF-160 endoscope advanced into the peritoneal cavity. Multiple adhesions between omentum & abdominal wall - cut with endoscopic snare. Detailed examination of spleen, liver, small and large intestine, gall bladder. Endoscope withdrawn into stomach. Gastric wall incision closed with 4 endoclips (Olympus).

Animal sacrificed.

Post-mortem examination: no damage to intraperitoneal organs. No bleeding. Good closure of gastric wall incision with endoclips. Gastric wall incision is located on anterior wall, close to antrum.

Oper:

Rising

Animal ID:

Surgeon: Kanteewey

Person Responsible*:

Protocol Number:

Telephone: pager: 36751

Telephone:

(*for post operative monitoring and care)

Surgery Date:

-REDACTED

Time Started:

9²⁰

Time Finished:

11⁵⁵

Anesthesia used (drugs and amount):

TKX 2cc, Pentathol 4cc IM
Isoflurane 1.5-2%

Analgesic drugs used:

none

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Acute experiment:

Needle-knife puncturing of the gastric wall. Jag-wire was inserted into the puncture site. Sphincterotomy placed over the wire. Gastric incision was enlarged to 2cm. No active bleeding. Upper endoscope (GIF-160) advanced into the peritoneal cavity. Good visualization of liver, gallbladder, spleen, large and small intestine. Few adhesions - separated by needle-knife. Endoscope withdrawn into stomach. Gastric wall incision closed with 6 endoclips (Olympus).

Animal sacrificed.

Post-mortem examination: no damage to internal organs. No bleeding. Gastric incision closed with clips. Gastric wall incision located on anterior wall between body and antrum.

Oper: [Signature]

Animal ID:

Surgeon:

Person Responsible*:

(*for post operative monitoring and care)

Protocol Number:

Telephone:

Telephone:

Surgery Date:

REDACTED

Time Started:

9³⁰

Time Finished:

12¹⁰

Anesthesia used (drugs and amount):

TKX 3cc, Pentathal 4cc IM
Isoflurane 1.5-2%

Analgesic drugs used:

Ø

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Acute experiment:

Gastric wall puncture with needle-knife.
Guide-wire inserted into the puncture site.
TTS Balloon advanced over the guide-wire.
Balloon distended to 20 mm. GIF endoscope
advanced to peritoneal cavity. Detailed
examination of small bowel, liver, large bowel,
gallbladder, spleen, pelvis. Endoscope withdrawn
to the stomach. Gastric wall incision closed
with 4 Olympus endoclips.

Animal sacrificed.

Post-mortem examination: no damage to intraperi-
toneal organs, no bleeding. Good closure of
gastric wall incision. Gastric wall incision
is on anterior wall on the border between
antrum and body.

Oper:

Raver

Animal ID:

Surgeon:

Person Responsible*:

Protocol Number:

Telephone: pager: 36751

Telephone:

(*for post operative monitoring and care)

Surgery Date:

REDACTED

Time Started:

9³⁰

Time Finished:

12³⁰

Anesthesia used (drugs and amount):

Tkx 4cc, Pentathial 4cc 1M
Isoflurane 1.5-2%

Analgesic drugs used:

none

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Pre-procedure

Weight - 110.1 lbs

Description of Operative Procedure and Day of Surgery Notes:

Pig's oral cavity cleaned with betadine. Pig draped with sterile drapes. Sterile endoscope (Olympus 61P-160) inserted inside the sterile overtube into the stomach. Gastric wall punctured with needle-knife and Jap-wire inserted into the puncture site. TTS balloon advanced over guide-wire and dilated to 20mm. Endoscope advanced into peritoneal cavity. Peritoneal cavity examined. Biopsy from right lobe of the liver - no bleeding. Endoscope withdrawn into stomach. Gastric wall incision closed with 4 endoclips. Animal recovered.

9/9/99 - The pig is awake, active. Eats regular food.

9/10/99 - Pig is active, no signs of distress. Eats regular food.

9/11/99 - Pig is active, moving around, eats food.

9/23/99 - Pig brought to animal lab, intubated. Weight - 118.5 lb

Upper endoscopy: well healed gastric incision. No clips left.

Animal Sacrificed. Post-mortem examination: Peritoneal culture obtained. Small collection of pus (microabscess) found next to gastric wall incision. Liver biopsy site and gastric wall incision healed completely.

ACUC ANIMAL POST OPERATIVE CARE AND MONITORING RECORD

Oper: K. K.

Animal ID:

Surgeon:

Person Responsible:

Protocol Number:

Telephone:

Telephone:

(*for post operative monitoring and care)

Surgery Date:

REDACTED

Time Started:

9²⁰

Time Finished:

12²⁰

Anesthesia used (drugs and amount):

TKX 4cc, Pentathal 4cc IM
Isoflurane 1.5 - 2%

Analgesic drugs used:

none

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Pre-procedure
Weight - 109.7 lbs

Oral cavity of the pig cleaned with betadine. Animal draped with sterile drapes. Sterile overtube with sterile endoscope (BIF-160) inside overtube advanced to stomach. Gastric wall punctured with sterile needle-knife and sterile jay-wire inserted into puncture site. Sterile TTS balloon advanced over the wire, dilated to 20 mm. Endoscope advanced to peritoneal cavity. Detailed examination. Biopsy from right lobe of liver - minor bleeding started, stopped by electrocautery. Endoscope withdrawn into stomach, incision closed with 6 endoclips. Animal recovered.

Oper: Kasey

9/17/99 - Pig is active, eats, moves around the cage.
9/18/99 - Pig appears well, no signs of distress. Eats well.
9/19/99 - Pig moves, eats, appears well and healthy.

9/29/99 - Animal sedated, intubated. EGD - well healed gastric incision. No clips left.

Animal sacrificed. Post-mortem exam: Gastric wall healed well. Peritoneal cultures obtained. Microabscess next to gastric wall incision with yellow pus. Liver biopsy site healed well.
Weight - 114 lbs

ACUC ANIMAL POST OPERATIVE CARE AND MONITORING RECORD

Oper: Kasey

Animal ID:

Surgeon:

Kantewary
An Singh

Person Responsible*:

Protocol Number:

SW99 M75

Telephone:

paper: 36751

Telephone:

(*for post operative monitoring and care)

Surgery Date:

REDACTED

Time Started:

9⁴⁰

Time Finished:

12⁴⁰

Anesthesia used (drugs and amount):

+ KX 4cc, Pentathol 4cc IM
+ Isoflurane 1.5-2%

Analgesic drugs used: none

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Pre-procedure

Weight - 113.2 lbs

Pig's oral cavity cleaned with betadine. Animal draped with sterile drapes. Sterile endoscope (61F-160) inside sterile overtube advanced into stomach. The stomach was lavaged with 1000cc of bio antibiotics (neomycin 40mg & polymyxin B sulfate). Gastric wall was punctured with sterile needle-knife, jag-wire inserted and sterile TTS balloon advanced over the jag-wire. Incision dilated to 20 mm. Endoscope advanced to peritoneal cavity. Detailed examination. Biopsy from (R) lobe of the liver - minor bleeding (stopped with electrocautery). Endoscope withdrawn into stomach, gastric wall incision closed with 4 endoclips. Animal recovered.

Oper: 11/9/99

9/30/99 - Pig is awake, active, eats, no signs of distress.

10/1/99 - Pig is active moves, eats. No signs of distress.

10/2/99 - Pig eats well, moves in the cage. No signs of illness.

10/13/99 - Animal is sedated, intubated. ECG: well healed gastric incision. No clips left.

Weight - 124 lbs.

Animal sacrificed. Post-mortem exam! Autoneal cultures obtained. No signs of infection inside peritoneal cavity. Well healed gastric wall incision and liver biopsy sites.

ACUC ANIMAL POST OPERATIVE CARE AND MONITORING RECORD

Kantewary

Animal ID:

Surgeon:

Kantsevar

Person Responsible*:

An: Singh

Protocol Number:

SW 99 M75

Telephone:

Perfer = 36751

Telephone:

(*for post operative monitoring and care)

Surgery Date:

REDACTED

Time Started:

9⁰⁰ AM

Time Finished:

1⁰⁰ PM

Anesthesia used (drugs and amount):

TKX 4cc
Pentathol 4cc IM
Isoflurane 1.5-2%

Analgesic drugs used:

none

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Pre-procedure

Weight 110.5 lbs

Description of Operative Procedure and Day of Surgery Notes:

Oral cavity cleaned with Betadine. Animal draped with sterile drapes. Sterile endoscope (61 F-160) inside sterile overtube inserted into the stomach. The stomach irrigated with 1000cc of bioflores (Neomycin 40 mg + polymyxin B sulfate). Gastric wall punctured with sterile needle-knife. Sterile Jap-wire introduced into the puncture site and sterile TTS balloon advanced over the wire. Balloon distended to 20 mm. Endoscope advanced into the peritoneal cavity. Detailed examination. Biopsy of (R) lobe of liver - no bleeding. Endoscope withdrawn into stomach. Gastric incision closed with 5 endoclips. Pig recovered.

Oper: Kantsevar

11/18/99 - The pig is awake, moves around the cage, eats.

11/19/99 - The pig is active, no signs of distress, eats well.

11/20/99 - The pig is active, eats well; moves, appears healthy.

12/2/99 - Animal is sedated, intubated. ECG: no clips left, gastric incision healed completely.

Animal is sacrificed. Post-mortem exam: Peritoneal cultures sent. No evidence of infection or bleeding inside peritoneal cavity. Well healed gastric wound and liver biopsy site.

ACUC ANIMAL POST OPERATIVE CARE AND MONITORING RECORD

Weight - 115.6 lbs

Kantsevar

Animal ID:

Surgeon:

Person Responsible*:

Kanithavey
Asst - Singh

Protocol Number:

Telephone:

Telephone:

SW 99 M 75

paper: 410 283 6251

(*for post operative monitoring and care)

Surgery Date:

REDACTED

Time Started:

1 pm

Time Finished:

5 pm

Anesthesia used (drugs and amount):

TKX 2cc, Pentathol 4cc IM
Isoflurane 1.5 - 2 %

Analgesic drugs used:

none

Time of anesthetic recovery*:

(*when animal is able to stand without assistance)

Description of Operative Procedure and Day of Surgery Notes:

Pre-procedure
weight - 113.5

Pig's oral cavity cleaned with betadine. Animal draped with sterile drapes. Sterile upper endoscope (GIF-160) inside sterile oviduct inserted into stomach. The stomach was lavaged with 1000 cc of biohesterics (neomycin + polymyxin sulfate). Gastric wall was punctured with sterile needle-knife. Sterile gas-wire inserted into the puncture site. Small TTS balloon was advanced over the wire and dilated to 20 mm. Endoscope advanced to peritoneal cavity. Multiple adhesions between stomach, omentum and anterior abdominal wall - separated with needle-knife. Biopsy from (R) lobe of liver - no bleeding. Endoscope withdrawn into stomach. Gastric incision closed with 5 endoclips. Animal recovered.

Oper - Kanithavey

11/19/99 - Animal is awake, moving, eats well.

11/20/99 - Animal appears healthy, eats well.

11/21/99 - Animal eats, moves, active. No signs of distress.

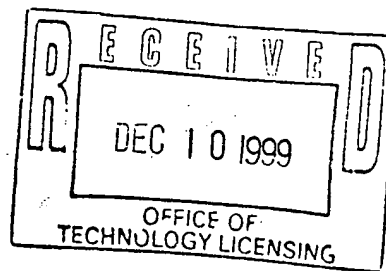
12/2/99 - Animal is sedated, intubated. EGD: No clips in stomach.

Gastric incision healed completely. Animal sacrificed. Post-mortem exam: Peritoneal cultures sent. No evidence of infection or bleeding. Gastric wall incision and liver biopsy healed completely. Weight - 120.4 lbs.

ACUC ANIMAL POST OPERATIVE CARE AND MONITORING RECORD

P. Asst.

Exhibit E



#1
DM-3634

1. Give the title of the invention.

TRANSGASTRIC PÉITONEOSCOPY

2. Provide the following information for each inventor:

- a) Full name: **Anthony Nicolas Kalloo, MD**
- b) Official title or position: **Clinical director, Division of Gastroenterology**
- c) Business phone **(410)955-9667**; fax **(410) 614-7340** and address : **1830 East Monument street, Room 419, Baltimore, MD, 21205**
- d) Home phone **(301)805-0797**, fax **(301) 464-5328** and address
- e) Citizenship - **USA**
- f) Social Security Number **219-98-0830**

2784-12

- a) Full name **Sergey Veniaminovich Kantsevov, MD, PhD**
- b) Official title or position **Clinical fellow, Division of Gastroenterology**
- c) Business phone **(410)614-3368**; fax **(410) 614-7340** and address : **1830 East Monument street, Room 420, Baltimore, MD, 21205**
- d) Home phone **(410)486-8119**, fax **(410)486-8119** and address **11302 Gilsan Street, Silver Spring, MD 20902**
- e) Citizenship - **USA**
- f) Social Security Number **219-35-1694**

3. For each JHU inventor, provide the name of the department in which the invention was made: **Department of Medicine, Division of Gastroenterology.**

RESEARCH SUPPORT INFORMATION

4. Provide the following information for each funding source under which the invention was developed:

- a) Complete title of grant **None**
- b) Granting agency **None**
- c) Award or contract number **None**

5. List the names of any and all institutions or companies which provided materials, software, or equipment to you under a Material Transfer Agreement (or similar type of agreement). **None**

6. List ALL other contributions to the development of the invention in terms of personnel, money, and facilities etc. **None**

INVENTION DESCRIPTION

7. Describe the invention completely, using the outline given below. Sketches, prints, photos, and any pertinent manuscript should be attached to this disclosure. Manuscripts generally following the outline are acceptable substitutes for this Section 7.

a) General Purpose - State in general terms the purpose and object of the invention. **This is an endoscopic procedure to examine peritoneal cavity.**

b) Background - Please list any journal citations, patents, general knowledge or other public information (prior art) which describes a similar invention. In addition, indicate how your invention overcomes the disadvantages of a similar invention.

Laparoscopy is an examination of peritoneal cavity. It currently performed through small incisions of anterior abdominal wall. Via these incisions rigid laparoscope (optical device) introduced into the peritoneal cavity. This is a surgical procedure, which carries risk of infection of the skin incisions, possible development of postoperative hernias, or scars, which may create cosmetic defects. Transgastric peritoneoscopy will be done via the stomach wall with the use of flexible endoscope. It will have excellent cosmetic result (no incisions of abdominal wall), no post-surgical scars or hernias.

c) Description and Operation - Describe completely the construction of the invention using reference characters to identify components in attached illustrations. Give a description of one complete operational cycle of the invention. If the invention relates to the synthesis or identification of a new composition of matter, describe the product in structural form, if possible, and the process of making it. Include all available information regarding its physical characteristics and all test data evidencing its utility. **We developed a new type of examination of peritoneal cavity: with the use of flexible endoscope and special sterile overtube with anchoring balloons incision of the gastric wall made in aseptic conditions from inside the stomach. One balloon inflated inside peritoneal cavity and the other one inflated inside the stomach. It will anchor the distal end of the overtube in the gastric wall (to prevent it from migration further into peritoneal cavity or back into the stomach), will isolate peritoneal cavity from the gastric cavity. It will also provide a conduit for manipulations inside the peritoneal cavity. Flexible endoscope will be introduced inside the peritoneal cavity for diagnostic examination and surgical manipulations. After procedure in completed, balloons will be deflated, overtube and endoscope pulled back into the stomach. Incision in gastric wall will be closed with endoscopic clips.**

8. Describe the closest known technology which pertains to the invention and point out how your invention differs from this technology, what problems it overcomes, and why it is considered to be an improvement.

See (7-b)

DISCLOSURES OF THE INVENTION

9. List any publications or planned disclosures (including abstracts and presentations) of the invention. If published, please include all journal citations and attach a reprint. If not yet published, please include a copy of the manuscript and the anticipated date of publication. In either case, list any other related references.

No publications yet.

10. Describe and list the date of any sale or public use of your invention in the United States. The description should specify if the use was (a) operational, (b) for testing purposes and (c) if there was any effort or intention to maintain the invention in secrecy after the operational use commenced.

11. List the names, addresses and affiliation of anyone to whom you have disclosed the invention and whether such disclosure was written or oral.

COMMERCIALIZATION

12. List the names of any companies (and a contact person, if known) who have contacted you regarding your research related to the invention. Include any companies who you feel may be interested in this technology or are doing similar research. **Many makers of endoscope and endoscopic equipment, such as "Olympus", "Pentax", "Microvasive", "Bard" will be very interesting in this invention. Many practicing gastroenterologists will be interested in this invention.**

In order for the Report of Invention to be complete, the attached Assignment of Invention document must be signed and dated by all JHU inventors and submitted with your ROI. Furthermore, the ROI must be signed and dated (a) by ALL inventors, (b) by two technically qualified witnesses who have read and understood the disclosure, and (c) by each JHU Department Director for ALL of the department(s) listed in #3 above. The Office of Technology Licensing can not process this report until it is complete with all necessary signatures.

Please submit reports to:

Nina Ossanna, Ph.D.
Director
Office of Technology Licensing
111 Market Place, Suite 906
Baltimore, Maryland 21202

Phone: (410) 347-3222
Fax: (410) 347-3201

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